REMARKS

Claims 1-26 are pending in this case. Claims 18-26 are withdrawn as directed to the non-elected Group II and Group III inventions. Claims 6-10 are withdrawn as directed to non-elected species.

The limitations of claims 4 and 11 have been incorporated into claim 1, and claims 4 and 11 have been canceled accordingly. Claims 3, 13, and 16 have been canceled as redundant in view of the amendment to claim 1. Claim 5 has been amended to depend from claim 1, and to correct a typographical error. Support for this amendment is found in the specification as originally filed at page 4, line 25-28. The claims remaining under consideration are 1, 2, 5, 12, 14, 15, and 17. In the prior response, it was stated that the elected species was covered by claims 1-5 and 11. As the elected species is also covered by claims 12, 14, 15, and 17, it is requested that those claims also be considered at this time.

Oath/Declaration

The examiner's objection to the Declaration submitted in this application is respectfully not understood. The Declaration has two alterations on the second page, one to inventor Claire Poulain's citizenship and the other to her address. In both cases, the inventor's dated signature appears immediately adjacent to the alterations. Thus, the date "28 June 07" and her signature "C Poulain" appear three times on that page: once in the space for the Inventor's signature, once next to the corrected citizenship, and once next to the corrected address. Applicants respectfully request the Examiner to explain what else, if anything, is required.

Claim rejection -- 35 USC 112

The claims were rejected as indefinite with respect to the use of "or" in two separate instances in claim 1. This language has been deleted from amended claim 1, thereby overcoming this ground of rejection.

Claim rejection -- 35 USC 103

The present invention is generally directed to a liquid pharmaceutical composition comprising an active ingredient and a preservative. Pursuant to the amendments herein, the

present claims are directed to the liquid composition wherein the active ingredient is levocetirizine or a pharmaceutically acceptable salt thereof, and the preservative is a mixture of methyl parahydroxybenzoate and propyl parahydroxybenzoate in a ratio of 9/1 expressed in weight, the mixture being present in an mount of more than 0 and less than 1.5 mg/ml of the composition. The amendments find support in the specification at least at page 3, lines 3-13; page 4, lines 3-5; and page 4, lines 25-28.

The claims stand rejected as obvious over Deitrich, (US 2004/0058896 A1). Dietrich is directed to a pharmaceutical compositions in which a coated pellet of an active ingredient can retain a desired functionality, even when subjected to further processing. In particular, Dietrich is directed to a preparation made of coated pellets of active ingredients in which the functionalities of the pellet coatings are maintained when the pellets are processed to dosage forms, such as by being shaped into tablets with excipients (Dietrich paras. [0002]-[0003]). Dietrich teaches (para. [0004]) that this can be accomplished by a preparation in which an active ingredient is essentially uniformly dispersed in an excipient matrix composed of one or more excipients selected from the group of fatty alcohol, triglyceride, partial glyceride and fatty acid ester. The composition of Dietrich is not limited to any particular active ingredient; in fact, Dietrich's list of possible active ingredients spans page 2, paragraph [0013] – page 18, paragraph [0401] of the reference. Hundreds of compounds are listed. Levocetirizine is one of the active ingredients listed, but it is not included in any of the examples or otherwise singled out. Preservatives are discussed only at paragraph [0439]. Nothing in that discussion suggests to one skilled in the art to use as a preservative a mixture of methyl parahydroxybenzoate and propyl parahydroxybenzoate in a ratio of 9/1 expressed in weight as presently claimed.

Dietrich's discussion of preservatives is part of a broader discussion of general excipients, also including flavorings, buffers, and emulsifiers, and the general amounts of each that can be used in the formed tablets. With regard to preservatives, Dietrich says, "The proportion depends on the preservative used and is normally from 0.1 to 4% by weight based on the solution or suspension ready for use." This is not a teaching of the use of the specific preservatives, in the specific proportions, with the particular active ingredient, as set forth in the amended claims. Indeed, Dietrich's broad disclosure teaches the opposite of the claimed invention, namely, that the choice of preservatives and their quantities is not critical. By

contrast, one aspect of the present invention is based on the discovery that the selection of the particular combination of preservatives and their proportion is indeed critical to the long term stability of this particular active ingredient.

One skilled in the art, searching for a solution to the problem of the stability of levocetirizine would not have turned to Dietrich, which teaches how to protect the functionalities of pellet coatings when the pellets are compressed or otherwise processed into tablets, or used in other pharmaceutical preparations. There is no motivation in the reference to choose levocetirizine as the active ingredient, as required in the amended claims, from among Dietrich's long list of possible active ingredients, or to use the particular preservatives in the particular proportions as claimed in the present application.

Even if one skilled in the art had read the Dietrich reference, he would not have had the idea to use a reduced amount of preservatives in order to obtain a levocetirizine composition stable over a long period of time. (specification, page 2, lines 11-15) It is respectfully submitted that the claims as amended are not obvious over the Dietrich reference.

The applicants' selection of the particular preservatives and amounts is not merely a routine selection by one of ordinary skill in the art based on the teachings of Dietrich. These particular preservatives and amounts lead to a result that is not suggested by the prior art, i.e., enhanced stability of the active ingredient, levocetirizine. Dietrich provides no reason to make the particular invention now being claimed, nor does Dietrich provide any teachings from which one of ordinary skill in the art could have reasonably predicted the results.

For all of the foregoing reasons, the applicants respectfully request reconsideration and withdrawal of this obviousness rejection. Further, should claim 1 as amended be found to be allowable, it is respectfully requested that withdrawn species claims 6-9 be considered as well.

Respectfully submitted,

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